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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/386,591

Applicant(s)

NEEDLEMAN ET AL.

Examiner

Janet L. Andres

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1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 16 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 3-7, 12, 13, 22-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 3-7, 12, 13, 22-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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RESPONSE TO AMENDMENT

1. Applicant's amendment filed 16 August 2001 is acknowledged. Claims 3-7, 12, 13, and 22-47 are pending in this application. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

2. The information disclosure statement filed 16 August 2001 in paper no. 10 has been considered in full.

Claim Rejections Withdrawn

3. The rejection of claims 3-7, 12, 13, and 22-39 under the provision of obviousness-type double patenting is withdrawn in response to Applicant's filing of a terminal disclaimer.

Claim Rejections Maintained/New Grounds of Rejection

4. The rejection of claims 3, 6, 7, 26, 29, 30, and 34-39 under 35 U.S.C. 103(a) is maintained and newly applied to new claims 40 and 42-46. Applicant argues that the reference cited by the Examiner addresses gene transfer. Applicant further argues that since the claimed DNA vaccine encodes the same peptide antigens as are disclosed in Applicant's earlier-filed applications, and thus the peptide antigens are predictive of a DNA vaccine. Applicant additionally cites *Donnelly* as teaching that immunization with DNA is "simple, robust, and effective".

Applicant's arguments have been fully considered but have not been found to be persuasive. The Eck and Wilson reference does in fact encompass problems with DNA vaccines. On p. 81, such vaccines are referred to as "gene-transfer mediated vaccination". The relevant issues are in fact the same: in order for the vaccine to be effective, the peptide must be synthesized. Thus, all of the potential problems described on p. 82 are relevant. The vector must

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be taken up by the cells, the peptides must be exported, and both DNA and mRNA must survive for a sufficient time to produce the peptide. As stated in the previous office action, the chemical characteristics of the DNA are entirely different from those of the peptide. Thus, while DNA that successfully produced peptide would be expected to elicit the desired result, such successful production is not predictable based on experiments using the peptide. That introduction of the peptide results in the production of antibodies does not indicate that introduction of the DNA will result in the production of the peptide. The *Donnelly* reference to the usefulness of DNA vaccines but does not provide sufficient direction for one of skill to predict whether or not any particular sequence could be used to generate a peptide *in vivo*. Thus, the Declaration is not evidence that the claimed invention was reduced to practice prior to the cited art.

Applicant additionally argues that the Thomas reference does not specifically teach which two regions are to be used, nor does the reference specify the length of the peptides. However, the instant claims are not drawn to any particular peptide, nor do they specify any particular length. What is claimed is a range of lengths that might ordinarily be used by one of skill as antigens. Thus the claims are not drawn to particular species, and, based on the teachings of Thomas et al., it would be obvious to one of ordinary skill to make and use the invention as claimed.

5. The rejection of claims 22, 25, 27, 28, 31, and 33 under 35 U.S.C. 112, first paragraph, is maintained and newly applied to new claim 41 and claims 23 and 24, which were inadvertently omitted from the previous rejection.

Applicant argues that considerable direction and guidance is provided in the specification. Applicant further argues that *Donnelly* teaches that DNA vaccines are simple and

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effective. Applicant further argues that the Eck and Wilson reference is concerned primarily with gene transfer to correct a deficiency. Applicant additionally argues that the Eck and Wilson reference is not current.

Applicant's arguments have been fully considered but have not been found to be persuasive. *Donnelly* teaches techniques for immunization with DNA but does not, as stated above, provide guidance that would allow one of skill to predictably use any particular DNA sequence as a vaccine. Eck and Wilson, as stated above, do address DNA vaccines and, further the considerations of vector uptake, DNA and mRNA stability, and exporting of the peptide are explicitly relevant to the production of antigen. More recent references, furthermore, continue to teach that use of DNA vaccines is problematic. Restifo et al. (Gene Therapy, 2000, vol. 7, pages 89-92), for example, teaches that "not a single naked nucleic acid vaccine has been approved for use in humans...nucleic acid vaccines have not been clearly demonstrated to have any convincing efficacy in the prevention or treatment of infection disease or cancer" (p. 89). Thus, recent reports continue to teach that the art is unpredictable and, without further guidance, one of skill would not be able to make and use the invention with an expectation of success.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

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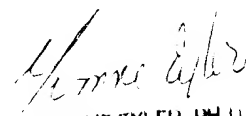
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
November 1, 2001


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600